## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

SYNGENTA SEEDS, INC.,	)	
Plaintiff,	)	
V.	) Civ. No. 02-13	31-SLR
MONSANTO COMPANY, DEKALB GENETICS CORP., PIONEER HI-	) )	
BRED INTERNATIONAL, INC., DOW AGROSCIENCES, LLC, and MYCOGEN PLANT SCIENCE, INC.	)	
and AGRIGENETICS, INC., collectively d.b.a. MYCOGEN	) )	
SEEDS,	)	
Defendants.	)	

## MEMORANDUM ORDER

At Wilmington this 22nd day of November, 2004, having reviewed various motions regarding the '865 patent, and the

<sup>&</sup>lt;sup>1</sup>Plaintiff has moved to dismiss defendants' counterclaims relating to the validity of unasserted claims. (D.I. 384) To the extent that motion relates to claims of the '865 patent, that motion is denied. The Federal Circuit, in Shelcore, Inc. v. Durhan Industries, Inc., 745 F.2d 621 (Fed. Cir. 1984), held that a district court retained jurisdiction over the alleged infringer's declaratory judgment with respect to invalidity. that case, the patentee had voluntarily dismissed with prejudice certain infringement claims, but had continued to assert infringement of other claims of the same patent. The court held that a patentee could not "unilaterally remove the validity issue because [the infringer's] counterclaim put validity of all the claims in issue." Id. at 624. Although the Federal Circuit, in Super Sack Manufacturing Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1054-1055 (Fed. Cir. 1995), concluded that a promise by a patentee not to assert patents against an infringer did divest the trial court of jurisdiction over the declaratory judgment because there was no longer a controversy, in that case the patentee withdrew the entire patent from controversy, not just

papers submitted in connection therewith;

judgment that certain claims of the '865 patent are invalid based upon the prior invention of Monsanto (D.I. 292), defendants' motion for summary judgment that the claims-at-issue of the '865 patent are invalid based upon the prior invention of Bt11 (D.I. 297), and plaintiff's motion for summary judgment that claim 19 of the '865 patent is infringed and not invalid (D.I. 278) are granted in part and denied part as follows:

- 1. Plaintiff brought the present action on July 25, 2002, alleging infringement of, inter alia, U.S. Patent No. 6,403,865 ("the '865 patent"). The '865 patent relates generally to fertile transgenic corn plants that express a gene encoding a Bacillus thuringiensis (Bt) insecticidal protein so as to cause mortality to European corn borers ("ECB"). (D.I. 293 at 2)
- 2. Facts as they relate to the Monsanto invention.

  In September of 1987, Fred Perlak, a scientist at Monsanto,

  designed the 5377 gene, which allowed corn plants to express Bt

  insecticidal proteins. (D.I. 294, ex. K at 3) The construction

  of this 5377 gene was completed by March 25, 1988. (Id.)
- 3. Monsanto scientists completed the construction of another modified Bt gene known as 5383 by April 15, 1988. (Id.)

  In an experiment entitled GUN147, Dr. Gail Petty bombarded corn

discrete claims. The court finds the distinction substantial.

cells with a transformation vector containing the 5383 gene.

(Id. at 3) GUN147 was conducted in June 1990. In November 1990, tests conducted on the bombarded corn cells showed expression of Bt insecticidal proteins at up to 20-30 ng/mg. (Id.) By January 20, 1991, a number of corn plants regenerated from the bombarded corn cells were found to be fertile. (Id. at 4) In March 1991, leaf tissue from progeny of these regenerated corn plants caused 100% mortality against ECB. (Id.) In the summer of 1991, some of the progeny plants were field-tested. (D.I. 294, ex. E at 82-83, 243) Nine of twenty-two progeny plants showed essentially no damage from ECB, whereas only three of twenty-two control plants exhibited essentially no damage. (D.I. 294, ex. F at MNP-0020104513)

4. In December of 1991 plants from experiments
GUN238 and GUN284 were greenhouse-tested for ECB resistance.

(D.I. 294, ex. K at 4) These plants expressed Bt insecticidal proteins at levels of over 100 ng/mg, and most showed essentially no damage from ECB. (Id.) In March of 1992, progeny from the GUN238 and GUN284 were greenhouse-tested and expressed Bt insecticidal protein at 200 ng/mg. (Id.) During May and June of 1992, twenty-five of these progeny plants were field-tested for ECB resistance. Most of the plants exhibited essentially no damage. (Id.) This result was confirmed by Ciba² scientist,

<sup>&</sup>lt;sup>2</sup> Ciba is the predecessor company of plaintiff.

Dean Christiansen, who noted that "[a] visit to Monsanto field plots confirmed Bt resistance to ECB . . . " (Id. at 5)

5. On March 19, 1992, Monsanto filed U.S.

Patent Application No. 92/855,857, which issued as U.S. Patent

No. 5,424,412 ("the '412 patent") on January 13, 1995. One

embodiment of the '412 invention is a

transgenic plant . . . comprising the chimeric plant described above. The resultant transgenic plants are capable of expressing a foreign gene which has been inserted into the chromosome of the plant cell.

The invention provides chimeric plant genes that when expressed in a transgenic plant provide greater quantities of the desired protein encoded by the structural coding sequence in the chimeric gene of the invention. The high protein levels impart important agronomic properties to the plant depending on which protein is present. For example, expression of a Bacillus thuringiensis crystal toxin protein protects the transgenic plant from insect attack.

('412 patent, col. 2, 11. 27-41) In example 10 of the '412 patent, corn plant cells were bombarded with a synthetic Bt gene encoding a Bt insecticidal protein. Plants regenerated from the cells were inoculated with 100 ECB eggs. Later these plants showed essentially no feeding damage. These plants were also shown to express Bt insecticidal protein at 200 ng/mg. ('412 patent, col. 21, 11. 32-42)

6. Facts as they relate to Bt11. In 1988, Sandoz entered into a research agreement with Monsanto to test some of Monsanto's Bt genes. On August 8, 1989, Sandoz received a synthetic Bt gene that contained extensive modifications from the

native sequence in the coding region. In 1989, Sandoz also obtained Monsanto's permission to sub-clone the Monsanto synthetic Bt gene into a Sandoz expression vector.

- 7. In 1991, Sandoz retained Hoechst to transform the synthetic Bt gene obtained from Monsanto into a corn plant.

  Sandoz sent Hoechst the Sandoz expression vector containing the Monsanto synthetic gene; Hoechst performed the transformation procedure, produced regenerated plants, and sent tissue samples from the regenerated plants to Sandoz in September 1991. One of these transformed corn lines eventually became known as "Bt11."
- 8. By November 1991, Sandoz conducted ELISA testing on Bt11 testing on Bt11 leaf tissue in the United States that detected a high level of Bt protein. The record contains evidence that Sandoz achieved a fertile Bt11 corn plant in the United States by April 1992. Field tests of Bt11 corn plants in the United States were initiated in May 1992.
- 9. Facts as they relate to Syngenta. In June of 1988, Ciba scientist Dr. Gary Pace prepared a project proposal, entitled "Transformation of Maize by Microprojectile Bombardment" ("M5 Project Proposal"), which described the procedures Ciba would use to transform corn via microprojectile bombardment.

  (D.I. 326 at B0001-B0008) The M5 Project Proposal primarily dealt with bombarding immature embryos from elite corn lines, although it noted that "[o]ther culture systems will also be used

as a target for transformation . . . " (<u>Id.</u> at B003, B005)

Type II callus is not mentioned as a possible target culture. In addition, immediately after stating that other cultures could be targeted, the M5 Project Proposal states the "[t]hese alternative techniques, however, will require development and improvement.

Therefore, they will be pursued secondarily to the demonstration of transformation using the in vitro, somatic embryo-based systems." (<u>Id.</u>)

10. On August 22, 1989, Dr. Koziel, a scientist with Ciba, generated a mRNA sequence of maize preferred codons that encodes a Bt protein. (Id. at B0031-33) In September 1989, Ciba initiated experiment TJ3 in which Type II callus was transformed with a hygromycin resistance gene. (Id. at B0087-88) By August 1990, Ciba confirmed that it had produced progeny transgenic maize plants from TJ3-82 that contained a hygromycin resistance gene. (<u>Id.</u> at B0089, B0448, B0451) In March 1991, Ciba scientists completed the construction of a synthetic maize optimized Bt gene. (Id. at B0104-B0106) In October 1991, Ciba scientists initiated the transformation experiments that produced Events 171 and 176, the plants described in the patents-in-suit. By April 3, 1992, Ciba scientists determined that the inbred corn plants from Event 171 expressed Bt protein in leaf tissue well above 5 ng/mg and inbred plants from Events 171 and 176 caused 100% mortality to ECB in laboratory bioassays. (Id. at B0044B0046, B0050, B0140-B0142, B0143-B0145, B0147-B0148, B0454-B0455)
On May 1, 1992, Ciba scientists determined that plants from Event
176 expressed Bt protein in leaf tissue well above 5 ng/mg. (Id.
at B0145) Between June 8 and June 26, 1992, Ciba scientists
determined that numerous progeny plants from Events 171 and 176
exhibited the Bt transgene and caused mortality to ECB in insect
bioassays. (Id. at B0046-B0048, B0160-B0091, B0195-B0198) Tests
indicated that the progeny plants expressed Bt at high levels.
By July 23, 1992, field tests of progeny plants of Events 171 and
176 provided control of ECB in the field. (Id. at B0208-B0214,
B0216)

patentee's invention has been made by another, prior inventor who has not abandoned, suppressed, or concealed the invention, § 102(g) will invalidate that patent." Apotex USA, Inc. v. Merck & Co., 254 F.3d 1031, 1035 (Fed. Cir. 2001). The Federal Circuit has observed that § 102(g) "retains the rules governing the determination of priority of invention." Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986) (quoting Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1444 (Fed. Cir. 1984)). To this end, a party alleging prior invention can establish that he was the first to invent by showing either: (1) he was first to reduce the invention and then

exercised reasonable diligence in attempting to reduce the invention to practice from a date just prior to the applicant's conception to the date of his reduction to practice.

See 35 U.S.C. § 102(g) ("In determining priority of invention . .

. there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was the first to conceive and last to reduce to practice, from a time prior to conception by the other."). As recognized by the Federal Circuit,

[a] principal purpose of § 102(g) is to ensure that a patent is awarded to a first inventor. However, it also encourages prompt public disclosure of an invention by penalizing the unexcused delay or failure of a first inventor to share the "benefit of the knowledge of [the] invention" with the public after the invention has been completed.

Checkpoint Sys. v. United States Int'l Trade Comm'n, 54 F.3d 756, 761 (Fed. Cir. 1995) (citing Paulik v. Rizkalla, 760 F.2d 1270, 1280 (Fed. Cir. 1985)).

mind of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." <a href="Hybritech">Hybritech</a>, 802 F.2d at 1376 (citations omitted). A conception must encompass all limitations of the claimed invention, and "is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive

research or experimentation." Singh v. Brake, 317 F.3d 1334, 1340 (Fed. Cir. 2002) (citations omitted). Put differently, every limitation must be shown to have been known to the inventor at the time the invention is alleged to have been conceived. Davis v. Reddy, 620 F.2d 885, 889 (C.C.P.A. 1980) (citing Schur v. Muller, 372 F.2d 546, 551 (1967); Anderson v. Anderson, 403 F. Supp. 834, 846 (D. D.C. 1975)). Because conception is a mental act, "it must be proven by evidence showing what the inventor has disclosed to others and what that disclosure means to one of ordinary skill in the art." In re Jolly, 308 F.3d 1317, 1321 (Fed. Cir. 2002) (quoting Spero v. Ringold, 377 F.2d 652, 660 (C.C.P.A. 1967)). The Federal Circuit has opined that a court should apply the "rule of reason" in determining conception. That is, the court should examine, analyze, and evaluate reasonably all pertinent evidence when weighing credibility of an inventor's story. Holmwood v. Sugavanam, 948 F.2d 1236, 1239 (Fed. Cir. 1991). Evidence in the form of documents does not need to be corroborated. See id. Rather, "[o]nly the inventor's testimony requires corroboration before it can be considered." Price v. Symsek, 988 F.2d 1187, 1195 (Fed. Cir. 1993).

13. Reduction to practice may either occur actually or constructively. Actual reduction to practice requires a showing by the inventor that "the invention is suitable for its intended purpose." Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1578 (Fed.

Cir. 1996). This may require actual testing for a complicated invention or may require only the complete construction of a prototype for a simple invention with obvious purpose and workability. See id. For a party alleging prior invention to establish that he actually reduced his invention to practice by testimony, he must corroborate his proffered testimony with independent evidence, which is evaluated under a rule of reason considering all the evidence. Loral Fairchild Corp. v. Matsushita Elec. Indus. Corp. Ltd., 266 F.3d 1358, 1363 (Fed. Cir. 2001). Notably, there is no requirement that the "prior invention" be commercialized in order for it to be actually reduced to practice. Steinberg v. Seitz, 517 F.2d 1359, 1363 (C.C.P.A. 1975). The key is whether the invention can be commercialized or has reached the point where "practical men [would] take the risk of commercializing the invention." <u>Goodrich v. Harmsen</u>, 442 F.2d 377, 383 (C.C.P.A. 1971). Constructive reduction to practice, in contrast, occurs when a party alleging prior invention files a patent application on the claimed invention. See Hybritech, 802 F.2d at 1376.

14. The party alleging prior invention must be able to show diligence "from a date just prior to the other party's conception to . . . [the date of] reduction to practice [by the party first to conceive]." Monsanto Co. v. Mycogen Plant Sci., Inc., 261 F.3d 1356, 1369 (Fed. Cir. 2002); Mahurkar, 79 F.3d at

1577. However, it is not necessary for a party claiming prior invention to drop all other work and concentrate solely on the particular invention involved. See Rines v. Morgan, 250 F.2d 365, 369 (C.C.P.A. 1957). There also need not be evidence of activity on every single day if a satisfactory explanation is evidenced. See Monsanto, 261 F.3d at 1369 (citations omitted). Additionally, determining whether the required "reasonable diligence" has been satisfied involves specific inquiry. Id. (citations omitted).

15. In order to avoid a finding that a prior invention was abandoned, suppressed, or concealed, the party alleging prior invention must take affirmative steps to make the invention publicly known. See Friction Div. Prods., Inc. v. E. I. Du Pont de Nemours & Co., 658 F. Supp. 998, 1013 (D. Del. 1987) (citing Ralston Purina Co. v. Far-Mar-Co, Inc., 586 F. Supp 1176, 1215 (D. Kan. 1984)). The Federal Circuit has explained that,

when determining whether an inventor has abandoned, suppressed, or concealed an invention, a period of delay between completion of the invention and subsequent public disclosure may or may not be of legal consequence. The delay may be inconsequential if, for example, it is reasonable in length or excused by activities of the inventor. Furthermore, there is no particular length of delay that is per se unreasonable. Rather, a determination of abandonment, suppression, or concealment has "consistently been based on equitable principles and public policy as applied to the facts of each case." A court must determine whether, under the facts before it, any delay was reasonable or excused as a matter of law.

Checkpoint, 54 F.3d at 761 (citations omitted).

- establish prior invention by clear and convincing evidence. See Apotex, 254 F.3d at 1037-38. If the party alleging prior invention does so, then the burden of production shifts to the patentee to produce evidence sufficient to create a genuine issue of material fact as to whether the party alleging prior invention abandoned, suppressed, or concealed the invention. See id. If the patentee carries this burden of production, then the party alleging prior invention may rebut the evidence of abandonment, suppression, or concealment with clear and convincing evidence. Id.
- Monsanto's GUN 238 and GUN 284 and Sandoz's Btll anticipate the claims at issue, the court denies the various summary judgment motions as there are genuine issues of material fact as to whether plaintiff conceived of the invention before the prior art described. The court does find the following reduction to practice dates have been established in the record: (a) Sandoz's Btll in April 1992; (b) Monsanto's GUN 238 and GUN 284 in May 1992; and (c) plaintiff's Events 171 and 176 in June 1992. The court further finds that, assuming plaintiff conceived of the invention in June of 1988 when it proposed the M5 Project, its work on that project amounts to diligence in reduction to practice. Therefore, there is no genuine issues of material fact

with respect to diligence.

18. The court denies the motions as they relate to infringement of claim 19 and as to invalidity under 35 U.S.C. \$ 102(e).

IT IS FURTHER ORDERED that defendants' motions for summary judgment based on written description (D.I. 299) and on 35 U.S.C. § 112,  $\P$  2 (D.I. 301) are denied, as the court simply does not have the resources to review these motions prior to trial.

Sue L. Robinson
United States District Judge